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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,234	01/11/2002	Paola Elisabetini	DI-5782	8974
29200	7590	11/16/2005	EXAMINER	
BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			CHOI, FRANK I	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/044,234

Applicant(s)

ELISABETTINI ET AL.

Examiner

Frank I. Choi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 83-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 83-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure of a range of about 100 mmol/L to about 173 mmol/L. The term "about" includes amounts above 173 mmol/L, however, there is no disclosure which indicates amounts above 173 mmol/L.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 83-95 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reinhardt et al. (US Pat. 5,211,643).

Reinhardt et al. expressly discloses a two part solution which is stored in a two chamber container used for CAPD in which concentrate A has a pH of 7.35 to 7.4 and contains 76 mmol of sodium hydrogen carbonate and concentrate B has a pH of 5.5 and contains 196 mmol of sodium chloride, 3.0 mmol of calcium chloride and 1.66 mmol of glucose falling within the scope of applicant's claims (Example 1, Column 6, lines 65-68, Column 2, lines 1-53, Figure 1).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant does not define what amounts are included or excluded by the term "about". The specification discloses ranges of about 160 mmol or less but then indicates that about 173 mmol/l is within the scope of the invention. As such, Applicant has not made any showing that amount of 196 mmol of is outside the range of "about 173" or that 76 mmols of sodium is outside the range of "about 100".

Claims 83-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US Pat. 5,871,477) in view of Watanabe et al. (US Pat. 5,122,516), Feriani et al. (US Pat. 4,630,727), van Bommel et al. and Reinhardt et al. (US Pat. 5,211,643).

Isono et al. disclose a two part dialysis composition, containing bicarbonate and electrolyte, in which a portion of the electrolyte, for example sodium, can be in the bicarbonate

part where the concentration of sodium is 90 to 150 mEq/L (Column 4, lines 60-68 , Column 5, lines 1-15, Column 8-65, Column 10, lines 44-58, Column 14, lines 10-68, Column 19, lines 12-68, column 20).

Watanabe et al. teach a two part composition, the first composition which contains an acid pH adjusting agent and sodium and the second composition which contains sodium and bicarbonate, which are stored separately and used for blood dialysis (Column 6, lines 13-68, Columns 7-10). A preferred embodiment is taught in which potassium is listed as a component in first composition but not the second composition (Column 6, lines 13-68, Columns 7-10).

Feriani et al. teach a two part composition contained in a twin-chamber bag in which the first chamber is filled with a bicarbonate-containing fluid and the second chamber is filled with an acid fluid (Abstract, Figures 1,2). An embodiment is taught where potassium is listed as a component in the bicarbonate containing solution but is not listed in the acid fluid (Column 6, lines 15-44). It is taught that the composition may be used for dialysis, hemofiltration and infusion (Column 6, lines 54-55). It is taught that for safety reasons it is preferred to have the bicarbonate in the compartment which has the discharge duct to prevent the acid part from being administered to the patient unmixed (Column 7, lines 3-21).

van Bommel et al. teach that hemodialysis and continuous renal replacement therapy can use the same fluids (Pgs. 271, Table 2, 272).

Reinhardt et al. discloses a two part solution which is stored in a two chamber container used for CAPD in which concentrate A has a pH of 7.35 to 7.4 and contains 76 mmol of sodium hydrogen carbonate and concentrate B has a ph of 5.5 and contains 196 mmol of sodium chloride, 3.0 mmol of calcium chloride and 1.66 mmol of glucose falling within the scope of applicant's claims (Example 1, Column 6, lines 65-68, Column 2, lines 1-53, Figure 1). It is

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disclosed solution B contains calcium and magnesium salts and concentrate A contains sodium hydrogen bicarbonate and that the level of acidity for the caramelization of glucose determines in which concentrates the remaining components, i.e. potassium chloride, sodium chloride and the like are placed (Column 6, lines 54-64). It is disclosed for the complete dialysis solutions the operative range for potassium is 04 mval/l and the preferred range is 1-3 mval/l (Column 4, lines 45-54).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a two-part composition comprising potassium in both the bicarbonate part and electrolyte part. However, the prior art amply suggests the same as it is known in the art to have two-part compositions in which potassium is contained either in the acid/electrolyte part or the bicarbonate part. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which potassium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. Further, it would have been well within the skill of one of ordinary skill in the art to have varying pH's in the bicarbonate part and acid/electrolyte part, including pH's falling within the claimed pH's, depending on the desired amounts of acid and bicarbonate in each part and the desired final pH of the mixture of the two parts. Also, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use a double chambered bag in which a first component cannot be administered to a patient without mixing with the second component for purposes of patient safety. Finally, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the two-part compositions for hemofiltration, including renal replacement therapy and infusion, with the expectation that the prior art dialysate composition would be suitable for the same.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The prior art discloses that it is known to have two-part compositions in which sodium is contained in the acid/electrolyte part and the bicarbonate part as well as potassium being in both, one or neither of the parts. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which sodium and potassium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. See *In re Burhans*, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.). Applicant has not shown any new or unexpected results of having equimolar amounts of sodium or potassium in one or both of the concentrates. Further, 15-40 mmol/l falls within the range of 160 mmol/L or less. With respect to amounts of about 100 mmol/L to about 173 mmol/L it is well within the skill of one of ordinary skill in the art, since it is disclosed that the sodium electrolyte may be in both compartments, to provide any amount of sodium including equimolar amounts, provided that the

combination results in a range of about 100 mmol/L to about 173 mmol/L. Reinhardt et al. disclose the use of a two chamber container (See figure 1) which separate stores the two parts in which the upper portion cannot be administered to the patient without first breaking the seal between the two compartments.

Applicant argues that Reinhardt is clearly distinguishable, however, as indicated above Applicant has not shown that the term "about" excludes either 76 mmol or 196 mmol. The fact that Watanabe does not disclose the specified amount of water, it is clear that based on the combination of the prior art that the amount of water which would be suitable is a liter. Further, Watanabe does not require the use of acetate (See claim 1 of Watanabe). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Contrary to Applicant's argument, Examiner has not used hindsight reasoning. However, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 170 USPQ 209, 212 (CCPA 1971). In this case, the teachings and motivation to arrive at the claimed invention are derived solely from the teachings of the prior art as indicated above.

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


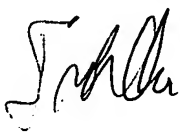
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

November 14, 2005



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600